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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11 07 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

578
09/540,758

Applicant(s)

KIMURA, ASA

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,6-8,21,26 and 27 is/are allowed.
- 6) ☒ Claim(s) 3,5,9-20,22-24,28-44 and 47-49 is/are rejected.
- 7) ☐ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 1-49 under the judicially created doctrine of obviousness-type double patenting is withdrawn, in light of the claim amendments.
3. The rejections of claims 1-49 under 35 U.S.C. 112, 2nd paragraph are withdrawn, in light of the claim amendments.

Claim Objections

4. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

5. Claims 3, 5, 22-24, and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 3 and 22: the recitation "wherein said plant has been manipulated to be male sterile" renders the claim indefinite. It is not clear if the claim is directed towards detasseled

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plants, or plants that have been transformed with a gene conferring male sterility. The following amendments are suggested: 1) in claims 3 and 22, replace "manipulated to be male sterile" with -detasseled-; 2) add a new claim 50 directed towards a method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 or 21 with a nucleic acid that confers male sterility, and a new claim 51 directed towards a male-sterile maize plant produced by the method of claim 50.

In claims 5 and 24: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 4 or 23.

In claim 23: the recitation "A tissue culture cells" renders the claim indefinite. A recitation appears to be missing, or the term "cells" should not be present.

In claim 40: the claim is indefinite because the recitation "comprising" in line 1 does not clearly indicate how many crosses are to be performed by the method. It is suggested that the recitation --F1 hybrid-- be inserted in claim 40, lines 1 and 6 before "maize".

6. Claims 9-20, 28-39, 41-43, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 27 March 2002 under item 8. Applicant traverses the rejection in the paper received 27 August 2002. Applicant's arguments were fully considered but were not found persuasive.

Applicant argues that because of the linked genes fixed in PH3AV, one can cross PH3AV with another line, select a plant expressing at least 2 PH3AV traits and a trait from the other plant line (response, paragraph bridging pages 8-9). However, the other parent could also express the some of the same traits as PH3AV and pass it on to the progeny. Further, the traits inherited from the other parent are not known, since the description of the other parent is not provided.

Applicants argue that the fact that technical tools to fully describe the unique characteristics of the full genome of PH3AV do not exist does not make the progeny lines derived from them any less entitled to adequate patent protection. Applicants continue, indicating that if the Office now views traits as an unacceptable means of description, other means of description by those of ordinary skill in the art may be used to satisfy written description. Applicants draw analogy to *Ex Parte Tanksley*, in which the Board held that the manner in which Applicants describe their invention is at their discretion (response, paragraph bridging pages 9-10 and page 10, 1st full paragraph). Applicants continue, arguing that amended claims 17, 33, and 36 limit the progeny covered to those within two outcrosses from PH3AV, and to those of ordinary skill in the art, this indicates that a line that is fewer crosses away from a starting line will be, as a whole, more highly related to the starting line, and the work of the original breeder in developing the starting line will be retained in the closely related progeny (response, paragraph spanning pages 10-11). However, the progeny will also retain the material inherited from the other plants involved in the crosses, which are not described by the specification. The progeny plants would be closely related to the other parent as well. Regarding Applicant's comment about the acceptance of traits by the Office to satisfy written

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description: Applicants are requiring the claimed progeny of the deposited line to express only two traits that also expressed by PH3AV. Clearly, plants express many more traits than just two. The traits enumerated in the claims are also not unique to PH3AV, and therefore describing a plant by saying that it expresses 2 particular traits does not distinguish it from any other plant that expresses the same traits. An organism with black hair and brown eyes does not distinguish it from any other individual of that species with those traits, even if one has the knowledge that only one of the parents has black hair and brown eyes.

Applicants also argue that the mere fact that progeny are not created fails to preclude their patentability, and possession can be shown by describing distinguishing identifying characteristics (response, page 11, 1st full paragraph). However, the claims indicate that only 2 traits need to be expressed, and these traits are expressed by other plants. The presence of the traits themselves does not distinguish the claimed plants from other plants that express them. Applicant argues that pedigree is a distinguishing characteristic that is in compliance with written description guidelines (page 11, 1st full paragraph). However, a pedigree does not describe the morphological and physiological traits of an organism, especially when all of the ancestors of an organism are not described. Further, it is not clear how a plant that is twenty generations removed from PH3AV is described by it. Applicant argues that the genetics of PH3AV is described by the ATCC deposit of its seed, and by limiting the progeny to 2 or less outcrosses, the concern that the progeny are only distantly related to PH3AV is addressed (response, page 11, 1st full paragraph to the paragraph bridging pages 11-12). However, the deposit only describes PH3AV. It does not describe the morphological and physiological traits

of any other plant. Further not all of the claims encompassing progeny plants are limited to 2 or less outcrosses.

Applicants argue that one of ordinary skill would know if PH3AV were utilized in a breeding program by looking at the breeding records, and that routine molecular techniques can be used to verify whether PH3AV is within the pedigree of a line. However, determination that PH3AV is an ancestor of a plant does not provide sufficient description of all of the morphological and physiological traits of that plant. Further, the specification does not describe any molecular determinants that one would need to identify any genetic material as having been derived from PH3AV. No description has been provided concerning molecular markers that are unique to the PH3AV genome, for example. Further, Applicant believes that the tools to fully describe the unique characteristics of the full genome of PH3AV do not exist.

Applicants emphasize that the influence of PH3AV cannot be removed from progeny that are 2 outcrosses removed from PH3AV, and the claimed progeny cannot be derived without the use of PH3AV as a parent. Applicants believe that this highlights the different perspective regarding claim scope between the Examiner and Applicant. Applicant contends that the Examiner's interpretation of the claims to progeny, as being of great breadth because a large number of plants could fall within its scope, ignores the essential limitation that only a plant developed through the use of PH3AV is within the scope of the claim (paragraph bridging pages 12-13). However, the influence of the other ancestors of the claimed progeny plants also cannot be removed. No description is provided at all as to the other ancestors, or the traits expressed by the progeny that are not expressed by PH3AV. As PH3AV is not the only ancestor of the progeny plants, the progeny necessarily express traits that are not expressed by PH3AV. Yet, no

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description is provided at all concerning those traits. Applicants argue that, to address the Examiner's concern that the PH3AV traits retained by the progeny may be derived from the non-PH3AV side of the pedigree, claim 14 has been amended to specify that the PH3AV traits were not derived from other plants used in the development of the claimed plant (response, page 13, 1st full paragraph). However, again, two traits are not sufficient to describe a plant when the traits themselves are not unique to PH3AV. Applicant has argued that PH3AV is unique, and that since PH3AV is described, that its descendents must also be described. However, while the combination of genes that produce PH3AV makes that line unique, Applicant does not provide any information as to why the genetic material itself unique. Applicant mentions that claims drawn to plants that contain a unique transgene make it allowable (paragraph bridging pages 9-10). However, Applicants here have not described the qualities of the genetic material of PH3AV that make it unique, other than references to the genetic material as a whole. Obviously, descendents do not inherit all of the genetic material of PH3AV. Regarding claims 11 and 30: the transgenes may be of any gene, including those that affect more than one trait. The morphological and physiological characteristics of any such plant are not described. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from PH3AV, which are not described. It is suggested that claims 11 and 30 be amended to list the types of transgenes contemplated in the specification, for example disease or pest resistance genes, provided the prior art teaches those isolated genes.

7. Claims 18-20 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards maize plant PH3AV, or a maize plant having all the morphological and physiological characteristics of PH3AV, further comprising one or more single gene conversions.

The specification teaches that single gene conversions, or introgression, of the disclosed maize plant through traditional breeding is contemplated (page 20, lines 15-30). However, the specification does not teach any PH3AV plants comprising single gene conversions. It is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created

in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is broadly drawn towards any maize plant, or parts thereof, wherein at least one ancestor is a plant of line PH3AV, expresses a combination of at least 2 traits that are not significantly different from PH3AV when determined at the 5% significant level and when grown in the same environmental conditions, and where the traits were derived from PH3AV and not from other plants utilized in the development of said plant.

The specification teaches the morphological and physiological characteristics of maize plant PH3AV (page 16, line 3 to page 19, line 50).

However, the specification does not teach how one may determine that a descendent of PH3AV, that expresses at least 2 of the traits enumerated in claim 14, could only have derived those traits from PH3AV, if any of its other ancestors also expressed those traits. The

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specification does not teach any determinants, such as molecular markers, that are unique to PH3AV and linked to the genes that govern the traits, that one skilled in the art would need in order to determine that the traits could only have been derived from PH3AV. Further, the specification does not teach the genes that govern the traits. It is not clear how one can determine that the traits could only have been derived from PH3AV if the specification does not teach the genes that govern the expression of those traits. If other ancestors of the claimed plant also expressed the traits, then the genes governing the traits could have been inherited from that ancestor(s). Further, Applicant believes that the tools to fully describe the unique characteristics of the full genome of PH3AV do not exist (response received 27 August 2002, page 9, 2nd full paragraph). In the absence of further guidance of these unique characteristics, undue experimentation would be required by one skilled in the art to determine that the genetic material of the claimed plant governing the traits enumerated in the claim was derived from PH3AV and not from any other ancestor that also expresses those traits. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Given the breadth of the claim, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102 & 103

9. Claims 14, 17, 33, 36, 41, and 43 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kramer (U.S. Patent No.

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6,124,534), for the reasons of record stated in the Office action mailed 27 March 2002 under item 9. Applicant traverses the rejection in the paper received 27 August 2002. Applicant's arguments were fully considered but were not persuasive.

Applicant argues that claim 14 has been amended to indicate the traits are not significantly different from PH3AV traits when determined at the 5% significance level and when grown in the same environmental conditions (response, paragraph bridging pages 15-16). However, the plant taught by Kramer expresses at least 2 of the enumerated traits, and has regions of adaptation in common with PH3AV. Applicant also argues that PH3AV is utilized to obtain the claimed plant and that, because PH3AV is not PH1K2, the plant of claim 14 cannot be obtained by any means other than by utilizing the seed or plant of PH3AV (response, page 16, 1st full paragraph). However, if a plant expresses any two of the traits enumerated in claim 14, the process of making the plant does not distinguish the plant itself from that taught in the reference. Amended claim 14 indicates that the traits were derived from PH3AV and not from other plants utilized in the development of said maize plant. However, the specification does not indicate how one would make this determination if other ancestors of the claimed plant do express the traits.

Applicant argues that claims 17 and 36 have been limited to a plant two crosses away from PH3AV, and that if an independent claim is non-obvious, any claim depending therefrom must be non-obvious (response, page 16, 2nd full paragraph). However, claims 17 and 36 are product-by-process claims, which may be properly rejected over prior art teaching the same product produced by a different process. See In re Thorpe, 227 USPQ 964,966 (Fed. Cir. 1985).

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Applicants argue that the plants of claims 41 and 43 are not one-cross removed from PH3AV (response, paragraph spanning pages 16-17). However, parent claim 40 does not clearly indicate that the method is only for producing F1 generation plants. It is suggested that claim 40 be amended as discussed above.

10. Claim 25 is objected to. Claims 1, 2, 4, 6-8, 21, 26, and 27 are allowed. Claims 3, 5, 9-20, 22-24, 28-44, and 47-49 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



A.M.
October 28, 2002

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